EXHIBIT 1

CONFIDENTIAL

EXPERT REPORT

Analysis of Distributor Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances on behalf of the City of Huntington and Cabell County, West Virginia

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pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs, because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

IV. Identifying Suspicious Orders Distributed in the City of Huntington and Cabell County, West Virginia

I have described in this report the ways in which Cardinal Health, McKesson, and AmerisourceBergen's inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed six suspicious order methodologies, some of which were utilized by one or more of the defendants. These methodologies are identified in the Report of Craig J. McCann as "Maximum Monthly, Trailing Six-month Threshold," "Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold," "Twice Trailing Twelve-month Average," "Three Times Trailing Twelve-month Average," "Maximum 8,000 Dosage Units Monthly," and "Maximum Daily Dosage Units." The purpose of each system was to identify suspicious orders that should not have been shipped unless the distributors' due diligence eliminated the suspicion of diversion.

With the exception of the method titled Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold,[116] under each of these methodologies, once an order by a pharmacy is flagged and the distributor does not conduct sufficient due diligence to dispel the suspicion of diversion, each subsequent order by that pharmacy is also flagged. The failure to conduct adequate due diligence on the initial triggering order, means that all subsequent orders by that pharmacy are likewise suspicious. This is consistent with the testimony of Thomas Prevoznik who testified on behalf of the DEA that distributors should not ship a suspicious order and should terminate all future sales to that same customer until they can rule out that diversion is occurring.[117] This is also consistent with Cardinal Health's statement in *Cardinal Health, Inc. v. Holder*, 1:12-cv-00185, that "as early as 2009" Cardinal's policy was to "terminate controlled-substance sales to the customer and report the termination to DEA" if the "customer's order could not be filled because it was suspicious[.]"[118] Cardinal also trained its people on this very same approach. The slide below is from one of Cardinal's training presentation in which they indicate that if a

[116] Under the Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold, when a transaction causes the number of dosage units shipped to a pharmacy in a month to exceed the highest number of dosage units shipped to the pharmacy in any one of the six preceding months, the dosage units of highest month in the preceding six months becomes threshold which is then applied in all subsequent months.

[117] Depo. of Thomas Prevoznik (Vol. II), 627:7-629:15.

[118] CAH_MDL_PRIORPROD_DEA12_00014702, 719.

customers, creating a conflict of interest in identifying accurate information. The fact that ABDC's chain retail pharmacy customers were exempt from this requirement abdicated ABDC's duty to identify suspicious orders to the customers themselves. Further, the Form 590 due diligence program itself was inconsistently implemented, leaving a lack of current and historical documentation of due diligence efforts that renders a robust, effective due diligence system impossible.

d. **AmerisourceBergen failed to *report* suspicious orders of controlled substances in violation of the *reporting requirement* set forth in 21 C.F.R. § 1301.74(b).**

Between 1998 and 2008, AmerisourceBergen timely reported zero suspicious orders from the CT1 jurisdictions. This is a blatant violation of the Reporting Requirement. Further, using any of the methodologies described in the Expert Report of Craig McCann, it is apparent AmerisourceBergen failed to report thousands of suspicious orders arising out of Huntington and Cabell County.[460]

I reserve the right to amend or supplement my opinions in this matter considering any new or additional information.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that to the best of my knowledge the foregoing is true and correct.

Date: August 3, 2020

James E. Rafalski

[460] *See* Section III above.